



## ENZYMATIC THERAPY INCORPORATED

*What **Better** feels like™*

**INTEGRATIVE THERAPEUTICS INC.**  
NF Formulas • PhytoPharmica  
Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 • F: 503.582.0467

**ENZYMATIC THERAPY®  
&  
PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 • F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 • F: 920.469.4418 (Phyto)

August 3, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Sedaplex®	Sedaplex supplies extracts of valerian, passionflower, hops, skullcap and jujube with L-theanine for gentle relaxation and restful sleep.*	Valerian Root Extract (Valeriana officinalis), Passionflower Aerial Parts Extract (Passiflora incarnata), Hops Strobile (Humulus lupulus), Jujube Seed Extract (Ziziphus jujuba), Skullcap Aerial Parts (Scutellaria lateriflora), L-Theanine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

8/3/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Financial Officer

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Sedaplex 1e



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Sedaplex®	Calcium, magnesium, and vitamin B6 are included to support a healthy nervous system.*	Vitamin B6 (as Pyridoxine Hydrochloride), Calcium (as Calcium Citrate), Magnesium (as Magnesium Oxide)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert C. Doster

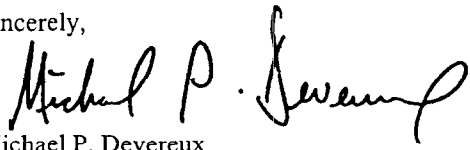
Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

8/3/04

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